Questions and Answers
Ortho Evra (norelgestromin/ethinyl estradiol)

1. What new action has taken place today, January 18, 2008 regarding Ortho Evra?

FDA has approved changes to the Ortho Evra label to include the results of an additional epidemiology study designed to evaluate the risk of developing serious blood clots, also known as venous thromboembolism (VTE), among women aged 15-44 when using Ortho Evra.

2. Is this information new?

In September, 2006, the Ortho Evra label reported the results of two epidemiologic studies sponsored by Johnson and Johnson to evaluate the risk of VTE in Ortho Evra users. The new labeling now includes results of a third epidemiologic study, as well as additional information on the risk of VTE in OrthoEvra users in one of the original studies, based on 17 months of data on new cases.

3. Why were these epidemiology studies done?

These epidemiology studies were conducted to evaluate the risk of developing a serious blood clot in women using Ortho Evra compared to women using different, commonly prescribed, oral contraceptive pills containing from 30-35 micrograms of the estrogen ethinyl estradiol and one of two progestins (norgestimate or levonorgestrel). Concern about this risk arose based on reports to FDA and to Johnson and Johnson of serious blood clots, which suggested that use of Ortho Evra might pose a greater risk of VTE, at least in some women, compared to use of oral contraceptives.

4. What information was learned from the three studies?

The studies were conducted using data from electronic health care claims. However, the studies were not conducted in exactly the same way, and results of the studies are different.

The first study was conducted by the Boston Collaborative Drug Surveillance Program (BCDSP). This study found that the risk of non-fatal VTE events

associated with the use of the Ortho Evra contraceptive patch is similar to the risk associated with the use of oral contraceptive pills (OCs) containing 35 micrograms of ethinyl estradiol and the progestin norgestimate. Analysis of 17 months of data on new cases not included in the original report showed a similar finding.

The second study, which included review of patients' charts, was conducted by another group of investigators (i3 Ingenix). Results of this study showed an approximately two-fold increase in the risk of medically-verified VTE events in users of Ortho Evra compared to users of OCs containing 35 micrograms of estrogen and the progestin norgestimate.

The third study, also conducted by BCDSP, compared the risk of non-fatal VTE events among users of Ortho Evra to the risk among users of OCs containing 30 micrograms of ethinyl estradiol and the progestin levonorgestrel. The results showed an approximately two-fold increase in the risk of VTE among the Ortho Evra users.

5. What does this information mean to women who are using or considering using Ortho Evra?

Even though the results of the three studies are conflicting, the results from two of the studies support FDA's concerns regarding the potential for use of Ortho Evra to increase the risk of blood clots in some women. The label continues to recommend that women with concerns or risk factors for thromboembolic events talk with their healthcare provider about using Ortho Evra versus other contraceptive options.

6. If a woman wants to change from the Ortho Evra patch to a birth control pill, what should she do?

She should talk to her health care professional. The health care professional will help her make this decision and select a different birth control option.

7. What other actions has the FDA taken with regard to Ortho Evra?

In November 2005, the FDA added information to the Ortho Evra label about the increased exposure to estrogen (based on drug blood levels) seen in women who use Ortho Evra compared with oral contraceptives containing 35 micrograms of ethinyl estradiol. Information about results from the first two epidemiology studies was added to the label in September 2006.

8. Where can I find more information on this?

If you have further questions regarding any medications, please contact the Center for Drug's Division of Drug Information at: 888-INFO-FDA (888-463-6332), or email us at: druginfo@fda.hhs.gov.

To view additional information on the use of Ortho Evra please visit our website.

Back to Top Back to Ortho Evra

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